5 510(k) Summary

JAN 0 7 2002

Submitted by:

Shire Biologics Inc.
30 Bearfoot Road
Northborough, MA 01532

Contact Person:

David Mantus, Ph.D.
Director, Regulatory Affairs

Date of Preparation:

October 12, 2001

1 Name and Address of Owner

Shire Biologics Inc.
30 Bearfoot Road
Northborough, MA 01532

2 Product Name

Trade Name: CIStem™

Common Name: Fluid Transfer Device

3 Claim of Substantial Equivalence

CIStem™ is substantially equivalent to the Needleless Transfer Device. Both the CIStem™ and the Needleless Transfer Device connect containers with drug and diluent to transfer and mix the two products so they can be drawn into a syringe and administered to the patient.

4 Device Description

CIStem™ is a closed reconstitution and instillation system used to deliver reconstituted drug through a catheter. This closed system is designed to prevent leakage and prevent exposure of drug to the environment, and is easy to use. The syringe is inserted into the

syringe socket of the device and the drug container is inserted into the other socket. A stopcock is used to direct and control the flow between the syringe, drug container and catheter. The syringe plunger rod is pushed to deliver liquid into the drug container. Next the plunger rod is pulled back and forth until all of the drug is mixed. Then the reconstituted drug in the syringe is delivered through the catheter.

There are two variations of CIStem™. These variations provide flexibility for the type of drug container. They both have the same intended use and similar safety features.

The materials that make up the fluid contact path in CIStem™ have passed ISO 10993-1 biocompatibility testing.

5 Intended Use

CIStem™ simultaneously attaches to the drug container, syringe with diluent and catheter adapter, forming a closed system. This configuration allows users to mix and deliver reconstituted drugs to the patient without exposure to potentially hazardous aerosols and spills that can occur during the reconstitution, administration and disposal processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2002

Shire Biologics, Incorporated
C/O Ms. Angela Rogers
Parexel International
Worldwide Regulatory Affairs
10182 Telesis Court
San Diego, California 92121

Re: K013523
Trade/Device Name: CIStem™
Regulation Number: K013523
Regulation Name: Fluid Transfer Device
Regulatory Class: II
Product Code: LHI
Dated: October 22, 2001
Received: October 23, 2001

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013523

Device Name: CIStem™

Indications For Use:

To transfer and mix drugs contained in two containers into a syringe for administration to the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Patricia Cusenza
(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K013523